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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,760	01/31/2002	James F. McGuckin JR.	10121/02401	2438
7590	01/26/2004			EXAMINER
Patrick J. Fay, Esq. FAY KAPLUN & MARCIN, LLP 17th Floor 100 Maiden Lane New York, NY 10038			BAXTER, JESSICA R	
			ART UNIT	PAPER NUMBER
			3731	10
DATE MAILED: 01/26/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

MK

Office Action Summary	Application No.	Applicant(s)	
	10/062,760	MCGUCKIN ET AL.	
	Examiner	Art Unit	
	Jessica R Baxter	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 November 2003.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-5 and 8-21 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) 1-5 and 8-16 is/are allowed.
 6) Claim(s) 17-21 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 05 November 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) The translation of the foreign language provisional application has been received.
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) Other: _____

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: 36, 55, 65 and 75. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. It is noted that the specification was amended to include these reference signs, however this amendment was not entered due to the fact that the paragraphs were numbered from [0033] to [0036], but the specification only contains numbered paragraphs to [0023].

2. The drawings were objected to as failing to comply with 37 CFR 1.84(p)(5) because they did not include the following reference sign(s) mentioned in the description: 16'. Correction is noted and the objection is withdrawn.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 9-12 and 16 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Correction is noted and the rejection is withdrawn.

5. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the

invention. Claim 21 recites the limitation "the second jaw moving mechanism" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 17, 18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,868,760 to McGuckin, Jr.

Regarding claim 17, McGuckin discloses a system for stapling tissue comprising: an operative head including a pair of opposed, curved tissue clamping jaws (FIG. 18 and 19) sized to pass through an esophagus (Column 1 lines 58-61), the jaws being moveable with respect to one another between an open tissue receiving configuration and a closed tissue clamping configuration (Column 13 lines 22-40), a first one of the curved jaws including a stapling mechanism (FIG. 23 lip 28) and a second one of the jaws including a staple forming anvil surface (FIG. 24 member 22), the stapling mechanism including staple slots through which staples are fired arranged in a row extending from a proximal end of the first jaw to a distal end thereof (FIG. 19 aperture 108); and a control handle which (operating control module 14), when the operative head is in an operative position within one of a patient's stomach and esophagus, remains outside the patient, the control handle including a first actuator (knob 38) for moving the jaws relative to one another and a second actuator for operating the stapling mechanism (trigger 36).

Regarding claim 18, McGuckin discloses that the tissue is located in the patient's stomach and the folds of tissue are coupled to one another (Column 1 lines 58-61).

Regarding claim 20, McGuckin discloses a tissue cutting mechanism for severing from the patient's body tissue located radially within the row of staples (Column 14 lines 28-63).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,403,326 to Harrison et al. in view of U.S. Patent No. 5,389,098 to Tsuruta et al.

Harrison discloses a method for stapling tissue comprising the steps of: inserting into a patient's mouth a flexible endoscope (Column 9 lines 9-14) device including an operative head having a pair of opposed, tissue clamping jaws (jaws 66), a first one of the jaws including a stapling mechanism (FIG. 8A.) and a second one of the jaws including a staple forming anvil surface (FIG. 8A); moving the jaws relative to one another from a closed position to an open tissue receiving position; drawing a folded, full-thickness portion of tissue from one of the patient's stomach and esophagus between the jaws (FIG. 8A); moving the jaws from the open position to the closed position to clamp the tissue between staple slots formed in the first jaw through which staples are fired by the stapling mechanism and the staple forming surface (Column 3 lines 44-55), wherein the staple slots are arranged in a row extending from a proximal end of the first jaw to a distal end

thereof (FIG. 8A); and actuating the stapling mechanism to drive staples out of the staple slots through the tissue and against the staple forming surface to couple the folds of tissue to one another (FIG. 8B). Harrison discloses the claimed invention except for the jaws being curved. Tsuruta teaches that it is known in the art to provide curved jaws for stapling the stomach since curved jaws can approximate the curve of the stomach. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Harrison with the curved jaws of Tsuruta in order to approximate the shape of the stomach more accurately.

Allowable Subject Matter

10. Claims 1-5 and 8-16 are allowed.

Response to Arguments

11. Applicant's arguments filed November 5, 2003 have been fully considered but they are not persuasive. Regarding claim 17, applicant argues that the prior art does not disclose a method comprising the steps of moving a stapling mechanism "relative to one another from a closed position to an open tissue receiving position *using a first jaw moving mechanism for gross adjustment of the position of the jaws relative to one another*" and "*adjusting the position of the jaws relative to one another using a second jaw moving mechanism for fine adjustment of the position of the jaws relative to one another.*" These limitations are not present in claim 17. Therefore, the rejection over McGuckin '760 is proper.

12. Applicaant argues that the device of Harrison '326 is not inserted through the mouth. However, Harrison specifically states that the device may be inserted through the esophagus instead of through an incision (Column 9 lines 7-16). Therefore, the rejection over Harrison '326 in view of Tsuruta '098 is proper.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
Art Unit 3731

JRB
Jrb

MJM
MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700